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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Application No. Applicant(s) 10/564,994 BEEBE ET AL. Office Action Summary Examiner Art Unit WU-CHENG Winston SHEN 1632 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 13 April 2009. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-132 is/are pending in the application. 4a) Of the above claim(s) 1-66.78-80.85-88 and 94-132 is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 67-77,81-84 and 89-93 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on 18 January 2006 is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

PTOL-326 (Rev. 08-06)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 10/18/2006.

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

DETAILED ACTION

This application is 10/564,994 a 371 of PCT/US04/23078 07/19/2004 which claims benefit of provisional application 60/487,932 filed on 07/18/2003, and claims benefit of provisional application 60/499,921 filed on 09/04/2003, and claims benefit of provisional application 60/526,585 12/04/2003.

Election/Restriction

Applicant's election with traverse of Group XI, Claims 67-77, 81-84, and 89-93, drawn to a pulse generator for generating electrical pulses comprising; a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude; and a control circuit for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse, in the reply filed on 04/13/2009 is acknowledged. The traversal is on the ground(s) that the examination of Groups XI, XII, and XIII together would not pose a serious burden on the Examiner. Applicant states that Group XI (claims 67-77, 81-84, 89-93) is drawn to a pulse generator for generating electrical pulses comprising; a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude; and a control circuit for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse. Group XII (claims 78-80) is drawn to the same pulse generator of Group XI, further comprising a delivery apparatus for delivering said first pulse and said second pulse to a load. Group XIII (claims 85-88) is drawn to the same pulse generator of Group

XI, further comprising a first switch coupled to and controlled by said control circuit, said first switch being operable to couple and decouple the first circuit from a load. A search of the prior art of Group XI would also necessarily encompass a search of the prior art for Groups XII and XIII and there will be no undue burden on the Examiner to examine these three groups together.

The traversal is not found persuasive because (i) the products of Group XII and XIII are structurally distinct from the product of Group XI as the delivery apparatus of the product of Group XII is not obvious component of the product of Group XI directed to a pulse generator, and a switch coupled to and controlled by a control circuit recited in the product of Group XII is not obvious component of the product of Group XI directed to a pulse generator, and (ii) as there is no common technical feature in all groups, the search for claims in Groups XI-XIII is distinct and not co-extensive and thereby presents search burdens on the Examiner. It is further noted, however, that search burden is not germane to PCT lack of unity practice.

Claims 1-132 are pending. Claims 1-66, 78-80, 85-88, and 94-132 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 03/19/2009.

Claims 67-77, 81-84, and 89-93 are currently under examination

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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 Claims 67-77, 81-84, and 89-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(I) Claim 67 reads as follows: A pulse generator for generating electrical pulses comprising: a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude; and a control circuit for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse.

The terms "long", "low", "short" and "high" in the limitations "a long duration and low voltage amplitude" and "a short duration and high voltage amplitude" recited in claim 67 are relative terms which render the claim indefinite. The term "long", "low", "short", and "high" are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 68-77, 81-84, and 89-93 depend from claim 67.

The specification teaches the following relevant disclosures: (i) One pulse type has a duration in the range of a classical electroporation pulse in the microsecond or the millisecond range (1 microsecond to 20 milliseconds). Such a pulse type is defined herein as a long pulse. The second type of pulse has a duration in the nanosecond range (1 to 300 nanoseconds), and defined herein as a short pulse (See paragraph [0078], US 2006/0269531, publication of instant application). It is acknowledges that the disclosure in paragraph [0078] provides definitions for the term "long duration" and "short duration" recited in claim 67. However, the limitation 0.1-20 milliseconds recited in claim 68 and the limitation 0.001-30 milliseconds recited claim 69 for

the first long pulse exceeds the defined long pulse range, 1-20 milliseconds, in the specification. Furthermore, the limitation 1-1000 nanoseconds recited in claim 71 exceeds the defined short pulse range, 1-300 nanoseconds, in the specification; and (ii) The specification discloses that for the long pulses, field amplitudes are low, on the order of hundreds/low thousands of V/cm (See paragraph [0074], US 2006/0269531, publication of instant application). However, the specification fails to provide clear definition of "low voltage amplitude" and "high voltage amplitude" recited in claim 67

(II) Related to (I) discussed in the preceding paragraphs, the term "high" in the limitation "high voltage power supply" recited in claims 81 and 89 is a relative term, which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 82-84 depend from claim 81 and claims 90-93 depend from claim 89. It is further noted that claims 81-84 and 89-93 depend from claim 67, which recites "a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude". However, claim 81 (which further limits the first circuit recited in claim 67) and claim 89 (which further limits the second circuit recited in claim 67) both recite "a high voltage power supply". Accordingly, it is unclear whether the limitations "the first circuit" and "the second circuit" recited in claim 67 are directed to (i) two structurally distinct entities or (ii) one entity that is intended for and capable of generation of both "low voltage amplitude" and "high voltage amplitude".

(III) Related to (II) discussed in the preceding paragraph, the phrase "a Blumlein configuration transmission line" recited in claim 90 is unclear because the metes and bounds the phrase cannot be determined in the absence of a clear definition of what a Blumlein configuration is disclosed in the specification. In this regard, the specification only provides an example of Blumlein configuration as shown in Fig. 7 (See paragraph [0084], US 2006/0269531, publication of instant application).

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 2. Claims 67-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Beebe et al. (Beebe et al., Nanosecond pulsed electric field (nsPEF) effects on cells and tissues: apoptosis induction and tumor growth inhibition, *IEEE Transactions on Plasma Science*, 30 (1): 286-292, Feb. 2002; this reference is listed as reference CC in the IDS filed by Applicant on 10/18/2006).

Claim 67 is directed to a pulse generator for generating electrical pulses comprising: a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude;

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and a control circuit for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse.

Claim interpretation: (a) The limitations "for generating a first pulse having a long duration and low voltage amplitude", "for generating a second pulse having a short duration and high voltage amplitude", "for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse" are considered as intended use of the circuits. The intended uses for recited circuits bear limited, if any, patentable weight for prior art rejections. (b) The limitations "the first circuit" and "the second circuit" recited in claim 67 is interpreted as either (i) two structurally distinct entities or (ii) one structural entity that is intended for and capable of generation of both "low voltage amplitude" and "high voltage amplitude".

Beebe et al. teaches a typical pulse generator for producing nsPEF (nanosecond pulsed electric field) effects consisting of a pulse-forming network (typically a coaxial cable of a strip line), a switch and the load. In the case of a matched load, where the resistance of the load is equal to the impedance of the pulse-forming network, the voltage pulse across the load has an amplitude of half the voltage applied to the pulsed-forming network. The pulse-forming network comprised five high-voltage 50Ω cables in parallel, which achieved the required 100 impedance for matched operation. The pulse duration from this device is twice the length of the cables or strip line, derived by the velocity of the electromagnetic wave in the dielectric of pulse-forming network. The switch is a simple spark gap in atmospheric air. Varying the gap distance sets the breakdown voltage. The load consists of $100~\mu$ l of cells suspension to be exposed to the nsPEF, and when HBSSW/o is used to suspend the cells, the electrical resistance is a $100~\Omega$ cm. The load

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is placed in an electroporation cuvette constructed with parallel aluminum plate electrodes 1 cm2 in area and separated by 0.1 cm, resulting in a load resistance of $R=10~\Omega$ (See right column, page 287, Beebe et al., 2002).

With regard to the limitations of claims 68-72, Beebe et al. teaches (i) electroporation occurs with pulse duration on the order of 0.1-10 ms (which reads on the limitations of claim 70 and 71) with electric fields on the order of kilovolts/centimeter (depending on the cell types and the cell suspension media), and (ii) exposure of suspensions of cells and tumor tissues to pulsed electric fields with durations of 10-300 ns (which reads on the limitations of claims 68 and 69) and electric fields lower or equal to 300 kV/cm (See right column, page 286, Beebe et al., 2002).

With regard to the limitations on electric field strength recited in claims 72-75, Beebe et al. teaches electric fields lower or equal to 300 kV/cm (which reads on the limitations recited in claims 72 and 73), and for example, pulses at 10, 60, and 300 ns at electric fields 150, 60, 40, 26 kV/cm (which reads on the limitations recited in claims 74 and 75; See Table 1, right column, page 288, Beebe et al., 2002).

With regard to the intervals between said first pulse and said second pulse recited in claims 76 and 77, Beebe et al. teaches 60 ns, 60 kV/cm, 1 s intervals (See table II, left column, page 289, Beebe et al., 2002).

Thus, Beebe et al. clearly anticipates claims 67-77 of instant application.

 Claims 67-72, 74-77, 81-84, and 89-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Gundersen et al. (Gundersen et al., US 2003/0170898, publication date

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09/11/2003, filed on 12/04/2002; this reference is listed as reference AD in the IDS filed by Applicant on 10/18/2006).

Claim 67 is directed to a pulse generator for generating electrical pulses comprising: a first circuit for generating a first pulse having a long duration and low voltage amplitude; a second circuit for generating a second pulse having a short duration and high voltage amplitude; and a control circuit for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse.

Claims 81-84 further limit the first circuit recited in claim 67. Claim 89-93 further limit the second circuit.

Claim interpretation: (a) The limitations "for generating a first pulse having a long duration and low voltage amplitude", "for generating a second pulse having a short duration and high voltage amplitude", "for controlling the timing of said first circuit and said second circuit to respectively generate said first pulse and said second pulse" are considered as intended use of the circuits. The intended uses for recited circuits bear limited, if any, patentable weight for prior art rejections. (b) The limitations "the first circuit" and "the second circuit" recited in claim 67 is interpreted as either (i) two structurally distinct entities or (ii) one structural entity that is intended for and capable of generation of both "low voltage amplitude" and "high voltage amplitude". (c) The limitations of claims 68 and 69 pertaining to pulse duration are interpreted any duration presented in the time unit of second because the recited ranges exceed the long pulse range defined in the specification, which is discussed in the rejection under 35 U.S.C 112 second, (I) of this office action)

With regard to claims 67-72, 74, and 75, Gundersen et al. teaches methods with combined long and short pulse technology, and in one embodiment, a "long" electric field pulse is applied to cell followed by a "short" electric field pulse. Gundersen et al. teaches that in one embodiment, the method includes applying at least one first electric field pulse to the cell sufficient to cause electroporation, incubating the cell with the therapeutic agent, and applying one or more second electric field pulses to one or more cells in the tissue, wherein each second electric field pulse has a pulse duration of less than about 100 nanoseconds. In a further embodiment, the pulse duration of the "short" pulse is less than about 1 nanosecond and the electric field is greater than about 10 kV/cm. In another embodiment, the pulse duration of the "long" pulse is greater than about 100 nanoseconds (See paragraph [0277], Gundersen et al., 2003/0170898, 2003). Gundersen et al. teaches that because the pulse characteristics require that the design of the pulse generator, matching of transmission line, and matching to the load (typically a cuvette with conductive solution containing cells with dielectric properties), must be engineered to match with these pulse shapes and pulse characteristics. In this regard, Gundersen et al. further teaches that a MOSFET-switched, inductive-adding pulse generator, using a balanced, coaxial-cable pulse-forming network and spark-gap switch for pulse shortening, was used. The pulse generators delivered electrical pulses to biological material in a variety of exposure modes, including, but not limited to, single-cell, detached-cell suspensions, and layers of cells in culture. The inductive adding pulse generator allowed application of the short pulses (typically about 5-10 kV and about 20 nanoseconds) [which reads on the limitations recited in 67-72, 74, and 75], thereby providing large amplitude electric fields at the electrical load (e.g., within the cuvette) (See paragraph [0089], Gundersen et al., 2003/0170898, 2003).

With regard to the intervals between said first pulse and said second pulse recited in claims 76 and 77, Gundersen et al. teaches that dose-response and time course of Jurkat cells in response to the UPSET pulse treatment: 20 to 50 repetitive UPSET shocks of 20 kv/cm, 20 nanoseconds with a 3 nanosecond rise time at 20 Hz caused significant apoptosis and gene expression changes in Jurkat cells. Gundersen et al. teaches that to characterize the dose-response of the Jurkat cells to the UPSET shocks, parameters were changed sequentially one parameter at a time. The field strength in the range of 10 kv/cm to 300 kv/cm, the pulse width in the range of 0.1 nanosecond to 100 nanoseconds, and the pulse frequency in the range of 1 hz to 10 khz were tested. The pulse pattern and the rising time of the pulses were also examined (See paragraph [0247], Gundersen et al., 2003/0170898, 2003). Gundersen et al. teaches that one skilled in the art will also understand that studies can also be performed at time intervals other than post 1 hour and post 6 hours after treatment (See paragraph [0116], Gundersen et al., 2003/0170898, 2003).

Pertaining to the limitations of the first circuit and the second circuit recited in claims 81-84 and 89-93, Gundersen et al. teaches that the load behaves as a parallel combination of a resistor and a capacitor, with an RC time constant, $\tau_L = \rho \epsilon \epsilon_0$, of approximately 3 nanoseconds. This is comparable to the pulse length. The pulse generator was designed to see a load impedance of $Z_L \sim 20~\Omega$ (See paragraph [0134], Gundersen et al., 2003/0170898, 2003). Gundersen et al. teaches a MOSFET-switched, inductive-adding pulse generator, using a balanced, coaxial-cable pulse-forming network and spark-gap switch [which reads on the limitation recited in claim 91 of instant application] for pulse shortening, was used (See Figures 21 of Gundersen et al., 2003, which is also provided below in this office action].

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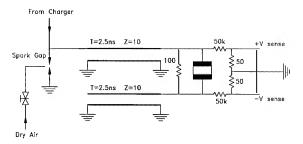
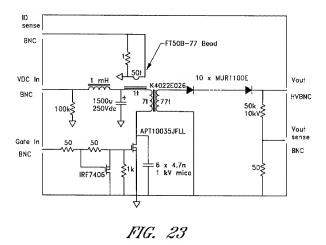


FIG. 21

Gundersen et al. teaches that the pulse generators delivered electrical pulses to biological material in a variety of exposure modes, including, but not limited to, single-cell, detached-cell suspensions, and layers of cells in culture. The inductive adding pulse generator allowed application of the short pulses (typically about 5-10 kV and about 20 nanoseconds), thereby providing large amplitude electric fields at the electrical load (e.g., within the cuvette). (See paragraphs [0089], Gundersen et al., US 2003/0170898, 2003). It is noted that the MOSFET-switched, inductive-adding pulse generator encompasses MOSFET transistors for determination of conductivity [See the middle of the diagram labeled APT10035JFLL in Figure 23 of Gundersen et al., 2003 provided next page in this office action]. Therefore, the MOSFET-switched, inductive-adding pulse generator reads on transistor for controlling electronical discharge of said capacitor to the load recited in claim 81 of instant application. This interpretation of MOSFET-switched, inductive-adding pulse generator and Figure 23 disclosed by Gubdersen et al. are supported by the disclosures in paragraph [0042] regarding a well-

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formed 50 kV pulse using small voltage switches (e.g. MOSFET transistors), and the disclosures in paragraph [0049] regarding APT5010LVR transistor, by Yampolsky et al., US 2002/0140464, publication date 10/03/2002.



With regard to the limitations recited in claims 82-84 regarding characteristics of transistor in the context of controlling electronical discharge, Gundersen et al., in addition to the disclosures of Figures 21 and 23 discussed above in this rejection, teaches that in one embodiment, the gate driver is the matching DEIC420 chip incorporating the same low inductance design as the MOSFET. The fast switching speed of the MOSFET gate causes large

oscillations in the drive circuit [which reads on the limitation insulated gate bipolar transistor recited in claim 84 of instant application]. Switching noise is sufficiently large to cause false triggering of the MOSFET after short pulses <60 nanoseconds. The gate pin noise with no filtering is 18.6 Vpeak having an oscillation frequency of 36 MHz. The gate drive IC propagates the noise through even to its logic level input pin. The DEIC420 driver VCC power pin is 15 V and shows 500 mV peak noise spike with or without gate filtering. Thus, power supply noise is not responsible for the large swings on the gate drive signal. The gate noise is also independent of MOSFET load and drain voltage (See paragraph [0176], Gundersen et al., US 2003/0170898, 2003). Gundersen et al. further teaches that saturable reactor filtering is placed in series with the gate driver and gate to reduce switching spikes at the gate. Drain fall time is slowed from 3.1 nanoseconds to 3.8 nanoseconds by the addition of gate filtering for 16.2 Vpeak noise and partial false triggering of the MOSEFET after turn-off from a 20 nanoseconds pulse. Sufficient inductance reducing the drain fall time to 4.2 nanoseconds results in 13.2 V peak noise on the gate and no false triggering of the MOSFET [which reads on the limitation handling sustained high currents without suffering thermal damage recited in claim 83 of instant application]. The chosen filter inductor includes a copper wire and two saturable reactors in parallel. Both of the saturable reactors are Toshiba Spike Killer SA7 x 6 x 4.5 magnetic cores with one turn each. Fig. 10 shows the cost in drain fall time to achieve noise suppression using varying combinations of paralleled conductors and saturable reactors. At 13.2 V and below, the MOSFET experiences no false triggering after a 20 nanosecond pulse (See paragraph [0177], Gundersen et al., US 2003/0170898, 2003).

With regard to the limitations recited in claims 90-93 regarding the configuration of second circuit, Gundersen et al., in addition to the disclosures of Figures 21 and 23 discussed above in this rejection, teaches that the *Blumlein configuration* (See Figure 21, Gundersen et al., 2003, shown in preceding page in this office action) includes two identical series connected *transmission lines* charged to a common voltage. Each individual line has a characteristic impedance half that of the load (See paragraph [0134], Gundersen et al., 2003/0170898, 2003). Gundersen et al. teaches that the maximum allowable charge time defines a maximum inductance, Ls, in series with the transmission line. The charging waveform is approximately one quarter of the period of the resonant circuit formed by this inductance and the load capacitance. This limits the inductance of the secondary winding of the high-voltage transformer (See paragraph [0153], Gundersen et al., 2003/0170898, 2003).

Thus, Gundersen et al. clearly anticipates claims 67-72, 74-77, 81-84, and 89-93 of instant application.

Conclusion

No claim is allowed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication from the examiner should be directed to WuCheng Winston Shen whose telephone number is (571) 272-3157 and Fax number is 571-2733157. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30
PM. If attempts to reach the examiner by telephone are unsuccessful, the supervisory patent
examiner, Peter Paras, Jr. can be reached on (571) 272-4517. The fax number for TC 1600 is
(571) 273-8300.

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/Wu-Cheng Winston Shen/ Patent Examiner Art Unit 1632